SUPPLEMENTAL MATERIAL

Contents

Appendix 1. Data extraction categories

- Name of first author
- Name of lead academic author
- Institutional address and email of lead academic author
- Categorisation of first, last and corresponding author as academic, funder or CRO
- Name of trial(s)
- Journal name
- Number of authors
- Number of authors involved in the statistical analysis
- Vaccines, drug(s) and device(s) used in trial
- Publication date
- Trial registration in a WHO approved registry (e.g. clinicaltrials.gov)
- Name(s) of trial industry funder(s)
- Verbatim extraction of author contributions statement
- Verbatim extraction of “Role of the funder statement”?
- Funder employee co-author(s) (yes/no)?
- Academic authors’ role in trial in relation to:
    - study design
    - study conduct
    - study analysis
    - study reporting
- Funder’s role in trial in relation to:
    - study design
    - study conduct
    - study analysis
    - study reporting
- Any use of a contract research organisation and their role in relation to:
    - study design
    - study conduct
    - study analysis
    - study reporting
- Lead academic author’s disclosed conflicts of interest
- Verbatim extraction of authors’ access to data and type of data
- Description of confidentiality agreements

Appendix 2. Survey questions

1. Contract
    a. Was any contract(s) or agreement(s) signed between you or other academic investigators and the trial funder (e.g. an investigator or publication agreement)?
    (If yes these questions appeared):
        i. Did it include a publication agreement (e.g. any trial publication needs approval from the funder prior to submission)?
        ii. Did it include a presentation agreement (e.g. any trial presentation needs approval from the funder before presentation)?
        iii. Did it include a confidentiality agreement (e.g. study results or protocol information may only be shared with third party after approval from the funder)?
        iv. Did it include other types of agreements, please describe (blank text box)?

2. Benefits of collaboration with the trial funder
    a. Please describe any benefits to your collaboration?
    b. Would you collaborate with this funder again?

3. Trial design
    a. Who decided what the comparator treatment should be (e.g. choice of active versus placebo comparator, type and dose of comparator drug or comparator device used)?
    b. Who decided which outcomes to measure in the trial?
    c. Who had the final say with regard to trial design?

4. Data analysis
    a. Who performed the actual statistical analysis of the trial data i.e. using statistical analysis software?
    b. Did you personally have access to the entire dataset?
    (If yes this question appeared)
        i. Did you actively use this access?

5. Manuscript
    a. Who wrote the draft manuscript?
    b. Who made the final decision on the content in the published manuscript (For example, which outcomes to report or how data should be interpreted)?

6. Collaboration with funder
    a. Was there any delay of publications due to funder?
    b. Were there any disagreements between you as academic investigator(s) and the funder concerning design, analysis, reporting of outcomes and/or writing the publication
    (If yes this question appeared)
        i. Please describe how these disagreements were managed by the funder?

7. If you have any additional comments you find relevant for this survey, please describe them here.

Appendix 3. Reasons for declining to participate

APPENDIX 3 TABLE 1 REASONS PROVIDED VIA EMAIL FOR NOT PARTICIPATING IN THE SURVEY	n
Not interested in participating	5
Lack of time	4
Do not wish to collaborate with the Cochrane Collaboration/The Nordic Cochrane Centre	2
Do not have the information requested/unable to help	2
Concerns with objectivity of the survey	1
Contact funder instead	1
Impossible I have joined industry	1

Appendix 4. Characteristics of the trials stratified by survey response type

APPENDIX 4 TABLE 1
CHARACTERISTICS OF THE TRIALS STRATIFIED BY SURVEY RESPONSE TYPE

	Responders*		Accessed survey without responding		Declined participation		Non-responders**	
Authorship	**n=80**	**%**	**n=10**	**%**	**n=16**	**%**	**n=91**	**%**
Median number of authors (range)	18	(1-48)	19	(10-36)	16	(5-35)	19	(6-40)
Academic and industry funder authors	68	85%	8	80%	15	94%	80	88%
Solely academic authors	12	15%	2	20%	1	6%	11	12%
Corresponding author academic	77	96%	10	100%	16	100%	86	95%
Corresponding author funder	3	4%	0	0%	0	0%	5	5%
Comparator								
Active treatment	33	41%	5	50%	6	38%	34	37%
Multiple arms (active treatment and placebo)	9	11%	1	10%	1	6%	16	18%
Placebo or no additional treatment	38	48%	4	40%	9	56%	41	45%
Role of funder								
Funder involved in design	66	83%	6	60%	16	100%	79	87%
Funder involved in conduct	58	73%	7	70%	13	81%	66	73%
Funder involved in data analysis	53	66%	8	80%	14	88%	70	77%
Funder involved in reporting	68	85%	8	80%	16	100%	74	81%
CRO involved in reporting	43	54%	7	70%	14	88%	55	60%
Lead academic author's reported conflicts of interest								
Conflict(s) of interest with funder***	58	73%	10	100%	14	88%	78	86%
Conflict(s) of interest with other company	11	14%	0	0%	1	6%	4	4%
No conflict of interest	11	14%	0	0%	1	6%	9	10%

CRO: contract research organisation.
Due to rounding the percentages may not add up to 100%
*7 authors only provided responses to some of the questions, 1 of them later emailed to say he did not have time to complete the survey, and he has been counted under Responders in this table
**3 unreachable authors' trials were not included in the non-responders.
***Those who had conflicts of interest with the funder could also have conflicts of interest with another industry company.

Appendix 5. Survey responses of lead academic authors

APPENDIX 5 TABLE 1

SURVEY REPORTED EXPERIENCE AMONG THE LEAD ACADEMIC AUTHORS

n=80*	Academic		Funder**		CRO**		Regulator		Other***	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	26	33%	12	15%	0	0%	6	8%	0	0%
Choice of outcomes	4	5%	23	29%	0	0%	5	6%	1	1%
Final say in design	29	36%	17	21%	0	0%	3	4%	0	0%
Conducted statistical analysis	21	26%	28	35%	7	9%	0	0%	1	1%
Drafted manuscript	53	66%	8	10%	0	0%	0	0%	1	1%
Final say on the published manuscript	52	65%	0	0%	0	0%	0	0%	1	1%

n=80*	Academic, funder and/or CRO collaboration		Academic and CRO collaboration		Funder and CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%	n	%	n	%
Choice of comparator	23	29%	1	1%	0	0%	4	5%	2	3%	6	8%
Choice of outcomes	35	44%	0	0%	0	0%	3	4%	3	4%	6	8%
Final say in design	24	30%	0	0%	0	0%	0	0%	2	3%	5	6%
Conducted statistical analysis	11	14%	0	0%	5	6%	0	0%	0	0%	7	9%
Drafted manuscript	8	10%	3	4%	0	0%	0	0%	0	0%	7	9%
Final say on the published manuscript	19	24%	1	1%	0	0%	0	0%	0	0%	7	9%

*7 authors only provided responses to some of the questions

**Funder and CRO also includes unacknowledged persons for the conducted statistical analysis and drafting of manuscript. In 7 trials the statistical analysis was conducted by a funder or CRO employee who was not a named author or contributor (3 of the 7 trials had unacknowledged funder employees, 3 trials had unacknowledged CRO employees and 1 trial had both an unacknowledged funder and unacknowledged CRO employee conduct the statistical analysis). In 5 trials the manuscript was drafted by a funder or CRO employee who was not a named author or contributor (4 of the 5 trials had an unacknowledged funder employee and 1 trial had an academic and an unacknowledged CRO draft the manuscript). Two trials had both an unacknowledged funder or CRO employee conduct the statistical analysis and an unacknowledged funder or CRO employee draft the manuscript. Thus, lead academic authors of 10 trials reported contributions to statistical analysis and/or drafting of the manuscript from unacknowledged persons.

***Other refers to one trial where it was unclear who had chosen outcomes and conducted statistical analysis and one where the academic did not know who drafted the manuscript and one where the academic found that the journal had the final say on the published manuscript.

Due to rounding the percentages may not add up to 100%.

Appendix 6. Comments to the survey questions

Different author comments have been separated by ";". Words have been replaced by "*pseudonyms"* to anonymise the author. Typos have been corrected.

Comments from Benefits of collaborating with the trial industry funder
Generating new research: "They were willing to do a global trial of an orphan disease that no other source would have EVER funded."; "Chance to move the field forward and to develop medicine based on prior lab discoveries"
Infrastructure and management: "Efficient operational management of multi-center trial"; "Much faster at helping address quality concerns and organizing than government"
*Funding: "*funding (much better than with governmental funding)"; "Fully funded trial with additional funding for translational research to be done by co-operative group"; "Study would not have been possible without funding which came as a donation, no strings attached."; "Funding (in this case, there would have been no funding to conduct the trial otherwise)"
*Publication: "*The *Journal X* paper! And more to come."; "Opportunity to author papers of important study results in high impact journals"
*Personal benefits: "*Being PI of a positive trial is always a benefit in CV and recognition"; "I was able to work closely with the study team to write and revise the protocol. We had a lot of discussions and I generally found that they listened to the advice offered by the trial steering committee. I was able to review the data prior to drafting the manuscript and we had a few calls to discuss the implications of the data and how to focus the paper. I found their statistical team generally helpful - at times they pushed back because I asked for a lot of additional analyses but they were generally accommodating. After the first draft was written, we definitely had some back and forth on messaging but ultimately, I was very comfortable with the final product and found that they listened to my point of view. Aside from the process itself, there are 'academic' benefits in the sense that this type of study is highly regarded by our institution and brings some notoriety to our institution. That being said, I would not object to all industry-sponsored studies being listed as 'the *Trial X* Investigators' or something similar - ultimately, despite our input, these are studies done by the company."; "consulting fee, publication of research"
*Miscellaneous: "*very fruitful and pragmatic collaboration with funder, allowing to transparently enrol patients in our country, and very transparent discussions of results, that is what I call "benefits""; "Not really any other than data analysis help"; "Industry funded the trial at substantial cost. They organized the sites. They created most of the study materials. Contractors did most of the work, contributed to design, analysis and reporting. Industry could do it themselves I assume. I do think the partnership brings value to both parties and patients."; "Input into protocol, input to data interpretation, development of scientific expertise in clinical trials and in the subject are of research, working with other key international leaders in the field, scientific excellence of the study sponsor, well-resourced study."; "The major benefits of industry collaboration for this investigator designed, led and run study were the provision of funding, labelled IMP and placebo, and logistical support."; "Transparency, faster results and execution, excellent funding."; "You can answer questions that academic or government funders cannot do. This mainly due to the scale of research funding needed and the risks taken. / There is better oversight of industry funded research. Much stricter auditing, monitoring and reporting of events etc."; "funding provided. Help in data analysis and publication provided"
*No benefits: "*No real benefits...."; "Nothing"

Comments from trial agreement between academics and funder
Miscellaneous: “Very thorough, well prepared With mutual respect”; “Non-disclosure Agreement / Clinical Trial Agreement w/ Payment schedule”
Comments from publication agreement
*Review and comment: “*the trial publication can be reviewed and comments provided. / but they do not get "approval" rights.”; “2-week period to allow for input, which the executive committee (independent of sponsor) could choose to ignore.”; “Not “approval” but rather an opportunity for them to make comments (which we could either take or reject)”
*Miscellaneous: “*Yes and aimed at journals With high impact factor”; “the contract explicitly stated that sponsor approval was NOT required for publication.”
Comments for presentation agreement
*Review and comment: “*Stipulated right of review by sponsor”; “they would be sent for review by sponsor but we have final say”; “I underline that there was an agreement, but in no way some kind of censorship.”
Comments for confidentiality agreement
Confidential until publication: “Until approval or public disclosure of the information.”; “No for results which are already in the public domain, obviously, but yes for all other unpublished data”; “Prior to presentation & simultaneous publication, the data was 100% embargoed for all parties”
Miscellaneous: “At some point I did sign confidentiality agreement. At beginning of trial and then before reviewing final data.“; “after publication.....”; “non-public information could not be shared with a 3rd party - for obvious reasons”; “the agreement stated that sponsor could request up to 30 days confidentiality if necessary for patent protection.”
Comments for other types of agreement
*Miscellaneous: “*The contract required the trial database to be transferred to the academic lead author's institution for statistical analysis and publication”; “adhere to good practices”; “Intellectual property clauses. Scope of work. Indemnification. Termination conditions. Many additional aspects...”
Comments for future collaboration with the funder
*Miscellaneous: “*I have done so for over 30 years”; “Such collaborations are essential (provided independent data analysis, publication and presentation is guaranteed) as trials of this size are rarely supported by charities or governmental institutions.”
Comments for choice of comparator
*Academics: “*The entire trial design was not influenced by the funder or any other party”
*Funder: “*As mentioned, this is a substudy of *Drug X* in the context of a RCT. The funder designed the study.
*Collaboration: “*The company has to obviously agree with the study design. They fund the trial.”; “There was a discussion between the pharma key people and the clinical investigator team about the best study design.”; “Funder, FDA, academic steering committee”; “Me and academic steering committee in discussions with industry partner. Industry partner has final say”; “Arduous, iterative process with input from FDA, academic steering committee, funder, and site investigators.”; “Research and development team of the sponsor. Input was obtained from study investigators.”
*Regulatory body: “*In accordance with FDA and EMA”;

"Having a placebo control in a double blinded trial design was recommended by the FDA"
*Miscellaneous: "*The sponsor did not want a placebo arm in the trial. We insisted upon it for safety evaluation and they ultimately agreed to a placebo arm with deferred treatment."; "The Steering committee specifically designed the trial - and we had an active comparator and the trial was neutral compared to the comparator. If we would have chosen *Drug X* (one might assume with industry or even guidelines that would be reasonable - maybe different finding) - but the SC chose the comparator"
Comments for choice of outcomes
Academic: "A steering committee of academic advisors, including me."; "Again, the funder had no influence on our primary and secondary outcomes."
Regulatory body: "FDA"
Collaboration: "Collaboration between funder, academics and of course the funder incorporated suggestions from regulatory bodies"; "Funder did primarily but they gathered many opinions including investigators and FDA/EMA"; "This was collaboration between academic investigators, regulators (Phase IV commitment) and industry sponsor"
Miscellaneous: "Entire trial was designed by the steering committee - this is actually less involvement than government sources often have in designing trials where they are hyper-focussed on cost"
Comments for final say in study design
*Academics: "*The principal investigator, which was the head of the research team."
*Funder: "*We advised the sponsor study team (extensively) and I would generally say that they listened, but they did not 'require' sign-off from the steering committee before finalizing the protocol so in that sense, they had final say."; "Again there was discussion but final saying by industry"
*Regulatory body: "*FDA of course- it was a regulatory study so they had to approve any study design"
*Collaboration: "*Again, making use of the funder's experience together"; "Funder and FDA"; "It was a combined decision of investigators, sponsor and finally FDA."
Miscellaneous: "On most aspects, academic steering committee members and funder were in agreement, so question of final say did not arise. On several aspects, FDA had final say, placing requirements that would not have been selected by the academic steering committee members or the funder. On other aspects, the community had say by having specialty societies issue guidances. These were sometimes poorly selected directives, but the funder felt it important to comply with international specialty society recommendations."
Comments for statistical analysis
*Academics: "*A statistician and I performed the analysis. No influence or contact with the funder in the whole process."
*Funder: "*Biostatistical team of the funder"; "Lots of analyses by a number of funder statisticians"
*CRO: "*Independent statistical bureau"; "The CRO agency was hired for this purpose."
*Collaboration: "*Jointly between Funder and Academic Investigators"; "Statistical consultant, along with study team and appropriate funder personnel"
Miscellaneous: "Independent biostatistician contracted by study sponsor and in-house industry biostatisticians."; "We analysed with independent academic and with the funder statisticians. Sometimes we have to rely on only the funder statisticians, which is less satisfactory. However SAPs and protocols are submitted to regulatory and editors before analysis and publication"; "Most of the analysis was done by the sponsor statistician who is listed as an author but the aggregated data were available to us (steering committee) and individual patient-level data was

available upon request. We were able to do additional analyses using these data - some of which ultimately ended up in the paper."; "Stats team employed by company. Monitored by independent data monitoring committee, not named, not part of sponsor or investigators."
Comments for access to data
Miscellaneous: "It varies from study to study"; "Although for person-level data, access was provided in response to questions. I had an aggregated data set, not person-level data."; "Not the ENTIRE dataset, but much of it and we were encouraged to ask for specific analyses."; "I had access to all the data but did not have access to the database. E.g., all analyses conducted in sponsor's dataset. Any analysis that we wanted was done."; "...in theory yes, but I didn't review all data"; "If I ask."
Comments for using data access
Miscellaneous: "The dataset was open for the research team and locked or the rest of the members"; "I anticipate some 30 high-quality papers will be published using this data set. 12 already published, 4 submitted and 10 currently in preparation"; "Not yet, but it is available to me for secondary analyses"; "Huge database housed at our institution. Could not possibly review every page, but all of the key outcomes reviewed carefully"; "I personally requested the independent statistician perform many analyses of the entire dataset, using shell tables that I designed. Every analysis I requested was performed."
Comments for drafting the manuscript
*Intro and discussion by academics methods and results by funder: "*I drafted the introduction and discussion sections, while the company scientific writers drafted the methodology and results sections."; "It was really a collaboration. The methods and initial draft of the results was written by a medical writer who works for the sponsor (and is acknowledged) but the intro and discussion were written by me and the last author on the paper. We then provided comment and revisions to the sections written by the sponsor and with back and forth iterations, we came to a final draft that was circulated to the other authors."
*Miscellaneous: "*I did and it was reviewed by the funder's scientific collaborators. Disagreements regarding data interpretation were hotly discussed but the academic point of view prevailed"; "In collaboration with the co-authors of the funder"; "This was an unusually coherent scientific partnership"; "Myself and an academic colleague"; "I wrote the first draft together with one funding representative and one other academic collaborator. The other authors commented on that and subsequent drafts."
Comments for final say on published manuscript
*Journal: "*Often also unfortunately - the journal has a larger and larger role"; "The journal!"; "In part, these decisions were also impacted upon by *Journal X* whose editorial policies regarding manuscript length and number of figures and tables forced us to consolidate. Ultimately, it was my responsibility to do this along with my academic colleagues and the statistician"
*Academics: "*Absolute no influence of the funder. We kept them out during the process."
Miscellaneous: "Company had review privilege but investigators had final say"; "There is input from the sponsors but the final decisions is with all authors, some who may work for funders"; "Primarily the Investigators/authors. Some guidance from funder."; "The funder and the authors did together...."; "Investigator in agreement with sponsor"

Comments for delay in publication
Miscellaneous: "There was a delay in publication, which was related to internal data check."; "Actually, less delay"; "It varies from trial to trial"; "Despite the stipulations in the contract, the manuscript was not sent to the funder prior to submission. This was considered unnecessary by both sides (despite the negative result, i.e. the medication is completely ineffective)"
Comments for disagreements with funder
Miscellaneous: "The sponsors were originally reluctant to run the study, but we won over by the academic advisors"; "The interpretation criteria stated in the protocol were partially contradicted by the data forcing to present data according to protocol and new criteria. This was actually requested by the publisher."; "When an external trial resulted positive, we needed to decide whether to place enrolment in the current trial on hold until a slightly earlier than planned interim analysis could be performed, or to continue enrolling. The funder would have preferred to continue enrolling. The academic steering committee voted 4 to 2 place the study on hold. The funder respected this decision and enrolment was placed on hold."
*Minor disagreements: "*Spirited discussion but agreement usually prevails"; "Small differences between PI/statistician and funder. The final version was exactly the version as proposed by PI/Statistician"; "The 'disagreements' were minor. Mostly on the points to emphasize in the discussion. Ultimately they accepted very close to our original version."; "Minimal. There were some analyses some investigators wanted to do but truly were beyond the scope of the primary goals of the trial."
Comments for how disagreements with funder were handled by the funder
Miscellaneous: "Want to postpone and change the wording"; "Back and forth emails and teleconferences. As noted, ultimately, they agreed on very close to our original version."; "We initially communicated about the disagreements via email, but with continued analysis and discussion, specific teleconferences were set up to improve communication efforts."; "The journal and I ended up determining the outcome"; "Other than the funder author, who gave appropriate scientific input, they were handled at arm's length."
Comments from additional comments
Miscellaneous: "For this research, academic independence was of importance for the academic staff. That is what was agreed with the funder, whether they liked it or not. We could provide the funder an academic setting, with highly skilled personnel to conduct the study. And that was what they wanted too. So for both groups it was a win-win."; "The study was somewhat unusual for pharma phase III studies, with greater input from the academic investigators, including study design, manuscript preparation, analyses etc."; "It is incredibly important that you distinguish between academically-led and performed trials, such as those conducted by my unit, and industry-led, conducted and analysed trials that may well have a degree of academic oversight but with most of not all of the rights remaining with the company"; "We had to manage possible conflicts of interest at our sites carefully."; "Discussions with the funder had a high intellectual and scientific level"; "The study and its publication brought prestige to *Society X*. Investigators are very keen to join hands for more studies now."; "Would have preferred to have the whole dataset. Got quite a lot but not everything"; "I found participating in this project to be a quite positive experience. I did not feel any pressure from the funder, believe I functioned in a totally independent manner, was able to obtain constructive feedback from my two primary academic colleagues as well as the other academic authors, and received no payment or grant for this project other than travel expenses for one

planning meeting.";
"In principle this type of partnership is vital to move the field forward. Rules for collaboration need to be set in advance, ideally on a contractual basis taking academic freedom as well as the needs of the industry into account, which can be tough, especially in the light of patent rights.";
"Further report not approvable or not approved by the sponsor"

Appendix 7. Subgroup analyses

Funder Problems stratified by Lead Academic's Conflicts of Interest

The nine academic authors with disclosed conflicts of interest (COIs) with an industry company other than the funder were not included in this subgroup analysis.

Responders with no COIs (n = 11)

One reported there was a delay in publication due to the funder doing an internal data check. Eight reported no delays in publication and two did not provide a response.

Similarly only one responder reported to have had minor disagreements about wording with the industry funder. Eight reported no disagreements but one added that the funder was more interested in the secondary outcome. Two did not provide a response.

Responders with COIs with the funder (n = 60)

Two reported there was a delay in publication due to the funder with one reporting that this was due to internal approval and one author responding that delay in publication varies from trial to trial. Fifty-four reported no delays and 4 did not provide a response.

Seven reported they had disagreements with the industry funder. Most of the authors added that the disagreements were minor. One reported that the funder was reluctant to run the study and one reported disagreements between the PI/statistician and the funder. Forty-nine reported no disagreements, but one added they had spirited discussions, but agreement usually prevailed. Four did not provide a response.

APPENDIX 7. TABLE 1A
CHARACTERISTICS OF THE 200 INDUSTRY-FUNDED TRIALS BY INTERVENTION TYPE

	Drug		Device		Vaccine	
Journal	**n**	**%**	**n**	**%**	**n**	**%**
New England Journal of Medicine	92	56%	9	35%	5	56%
The Lancet	49	30%	10	38%	3	33%
JAMA	17	10%	7	27%	1	11%
Annals of Internal Medicine	4	2%	0	0%	0	0%
JAMA Internal Medicine	2	1%	0	0%	0	0%
BMJ	1	1%	0	0%	0	0%
Comparator						
Active treatment	55	33%	20	77%	4	44%
Multiple arms (active treatment and placebo)	27	16%	0	0%	0	0%
Placebo or no additional treatment	83	50%	6	23%	5	56%
Authorship						
Median (range)	18	(1-48)	17	(6-35)	27	(17-31)
Academic and industry funder authors	151	92%	13	50%	9	100%
Solely academic authors	14	8%	13	50%	0	0%
1st author academic	162	98%	26	100%	8	89%
1st author funder	3	2%	0	0%	1	11%
Last author academic	127	77%	23	88%	4	44%
Last author funder	35	21%	2	8%	5	56%
Last author CRO	1	1%	1	4%	0	0%
Last author other*	2	1%	0	0%	0	0%
Corresponding author academic	160	97%	26	100%	6	67%
Corresponding author funder	5	3%	0	0%	3	33%
Lead academic author's reported conflicts of interest						
Conflict(s) of interest with funder**	139	84%	19	73%	7	78%
Conflict(s) of interest with other company	12	7%	2	8%	0	0%
No conflict of interest	14	8%	5	19%	2	22%

CRO: contract research organisation.
Due to rounding the percentages may not add up to 100%
*Other refers to an author employed by an industry company other than the industry funder and one author where it was unclear if the affiliation was a CRO or private clinic.
**Those who had conflicts of interest with the funder could also have conflicts of interest with another industry company.

APPENDIX 7. TABLE 1B
CHARACTERISTICS OF INDEPENDENT ACADEMIC INDUSTRY-FUNDED TRIALS AND TRIALS WITH FUNDER INVOLVEMENT

	Independent* n=8		Funder Involved n=192	
Journal	**n**	**%**	**n**	**%**
New England Journal of Medicine	1	13%	105	55%
The Lancet	2	25%	60	31%
JAMA	3	38%	22	11%
Annals of Internal Medicine	1	13%	3	2%
JAMA Internal Medicine	1	13%	1	1%
BMJ	0	0%	1	1%
Comparator				
Active treatment	4	50%	75	39%
Multiple arms (active treatment and placebo)	0	0%	27	14%
Placebo or no additional treatment	4	50%	90	47%
Authorship				
Median (range)	13	(6-21)	19	(1-48)
Academic and industry funder authors	0	0%	173	90%
Solely academic authors	8	100%	19	10%
1st author academic	8	100%	188	98%
1st author funder	0	0%	4	2%
Last author academic	8	100%	146	76%
Last author funder	0	0%	42	22%
Last author CRO	0	0%	2	1%
Last author other**	0	0%	2	1%
Corresponding author academic	8	100%	184	96%
Corresponding author funder	0	0%	8	4%
Lead academic author's reported conflicts of interest				
Conflict(s) of interest with funder***	4	50%	161	84%
Conflict(s) of interest with other company	0	0%	14	7%
No conflict of interest	4	50%	17	9%

CRO: contract research organisation.
Due to rounding the percentages may not add up to 100%
*Independent trials defined as trials with no funder or CRO co-authors and no funder or CRO involvement in the design, conduct, analysis and reporting of the trial.
**Other refers to an author employed by an industry company other than the industry funder and one author where it was unclear if the affiliation was a CRO or private clinic.
***Those who had conflicts of interest with the funder could also have conflicts of interest with another industry company.

APPENDIX 7. TABLE 2A

SURVEY REPORTED EXPERIENCE AMONG THE LEAD ACADEMIC AUTHORS STRATIFIED BY INTERVENTION TYPE

Drug n=61	Academic		Funder*		CRO*		Regulator		Other**	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	20	33%	11	18%	0	0%	5	8%	0	0%
Choice of outcomes	17	28%	3	5%	0	0%	3	5%	1	2%
Final say in design	23	38%	14	23%	0	0%	1	2%	0	0%
Conducted statistical analysis	18	30%	25	41%	3	5%	0	0%	1	2%
Drafted manuscript	41	67%	7	11%	0	0%	0	0%	1	2%
Final say on the published manuscript	39	64%	0	0%	0	0%	0	0%	1	2%

Drug n=61	Academic, funder and/or CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%
Choice of comparator	18	30%	4	7%	0	0%	3	5%
Choice of outcomes	29	48%	3	5%	2	3%	3	5%
Final say in design	18	30%	0	0%	2	3%	3	5%
Conducted statistical analysis	10	16%	0	0%	0	0%	4	7%
Drafted manuscript	8	13%	0	0%	0	0%	4	7%
Final say on the published manuscript	17	28%	0	0%	0	0%	4	7%

Device n=13	Academic		Funder*		CRO*		Regulator		Other**	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	4	31%	0	0%	0	0%	1	8%	0	0%
Choice of outcomes	5	38%	0	0%	0	0%	1	8%	0	0%
Final say in design	5	38%	1	8%	0	0%	2	15%	0	0%
Conducted statistical analysis	3	23%	2	15%	3	23%	0	0%	0	0%
Drafted manuscript	10	77%	0	0%	0	0%	0	0%	0	0%
Final say on the published manuscript	10	77%	0	0%	0	0%	0	0%	0	0%

Device n=13	Academic, funder and/or CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%
Choice of comparator	5	38%	0	0%	1	8%	2	15%
Choice of outcomes	5	38%	0	0%	0	0%	2	15%
Final say in design	3	23%	0	0%	0	0%	2	15%
Conducted statistical analysis	3	23%	0	0%	0	0%	2	15%
Drafted manuscript	1	8%	0	0%	0	0%	2	15%
Final say on the published manuscript	1	8%	0	0%	0	0%	2	15%

Vaccine n=6	Academic		Funder*		CRO*		Regulator		Other**	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	2	33%	1	17%	0	0%	0	0%	0	0%
Choice of outcomes	1	17%	1	17%	0	0%	1	17%	0	0%
Final say in design	1	17%	2	33%	0	0%	0	0%	0	0%

Conducted statistical analysis	0	0%	1	17%	1	17%	0	0%	0	0%
Drafted manuscript	2	33%	1	17%	1	17%	0	0%	0	0%
Final say on the published manuscript	3	50%	0	0%	0	0%	0	0%	0	0%

Vaccine n=6	Academic, funder and/or CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%
Choice of comparator	1	17%	0	0%	1	17%	1	17%
Choice of outcomes	1	17%	0	0%	1	17%	1	17%
Final say in design	3	50%	0	0%	0	0%	0	0%
Conducted statistical analysis	3	50%	0	0%	0	0%	1	17%
Drafted manuscript	1	17%	0	0%	0	0%	1	17%
Final say on the published manuscript	2	33%	0	0%	0	0%	1	17%

*Funder and CRO also includes unacknowledged persons for the conducted statistical analysis and drafting of manuscript

**Other refers to one trial where it was unclear who had chosen outcomes and conducted statistical analysis and one where the academic did not know who drafted the manuscript and one where the academic found that the journal had the final say on the published manuscript.

Due to rounding the percentages may not add up to 100%.

APPENDIX 7. TABLE 2B

SURVEY REPORTED EXPERIENCE AMONG THE LEAD ACADEMIC AUTHORS STRATIFIED AS INDEPENDENT ACADEMIC, INDUSTRY-FUNDED TRIALS AND TRIALS WITH FUNDER INVOLVEMENT

Independent n=4	Academic		Funder*		CRO*		Regulator		Other**	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	4	100%	0	0%	0	0%	0	0%	0	0%
Choice of outcomes	4	100%	0	0%	0	0%	0	0%	0	0%
Final say in design	4	100%	0	0%	0	0%	0	0%	0	0%
Conducted statistical analysis	4	100%	0	0%	0	0%	0	0%	0	0%
Drafted manuscript	4	100%	0	0%	0	0%	0	0%	0	0%
Final say on the published manuscript	4	100%	0	0%	0	0%	0	0%	0	0%

Independent n=4	Academic, funder and/or CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%
Choice of comparator	0	0%	0	0%	0	0%	0	0%
Choice of outcomes	0	0%	0	0%	0	0%	0	0%
Final say in design	0	0%	0	0%	0	0%	0	0%
Conducted statistical analysis	0	0%	0	0%	0	0%	0	0%
Drafted manuscript	0	0%	0	0%	0	0%	0	0%
Final say on the published manuscript	0	0%	0	0%	0	0%	0	0%

Funder involved n=76	Academic		Funder*		CRO*		Regulator		Other**	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	22	29%	12	16%	0	0%	6	8%	0	0%
Choice of outcomes	19	25%	4	5%	0	0%	5	7%	1	1%
Final say in design	25	33%	17	22%	0	0%	3	4%	0	0%
Conducted statistical analysis	17	22%	28	37%	7	9%	0	0%	1	1%
Drafted manuscript	49	64%	8	11%	0	0%	0	0%	1	1%
Final say on the published manuscript	48	63%	0	0%	0	0%	0	0%	1	1%

Funder involved n=76	Academic, funder and/or CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%
Choice of comparator	24	32%	4	5%	2	3%	6	8%
Choice of outcomes	35	46%	3	4%	3	4%	6	8%
Final say in design	24	32%	0	0%	2	3%	5	7%
Conducted statistical analysis	16	21%	0	0%	0	0%	7	9%
Drafted manuscript	11	14%	0	0%	0	0%	7	9%
Final say on the published manuscript	20	26%	0	0%	0	0%	7	9%

*Funder and CRO also includes unacknowledged persons for the conducted statistical analysis and drafting of manuscript

**Other refers to one trial where it was unclear who had chosen outcomes and conducted statistical analysis and one where the academic did not know who drafted the manuscript and one where the academic found that the journal had the final say on the published manuscript.
Due to rounding the percentages may not add up to 100%.

APPENDIX 7. TABLE 2C

SURVEY REPORTED EXPERIENCE AMONG THE LEAD ACADEMIC AUTHORS STRATIFIED BY COLLABORATION STATUS

Collaborating with funder/ would in the future n=67	Academic		Funder**		CRO**		Regulator		Other***	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	23	34%	10	15%	0	0%	6	9%	0	0%
Choice of outcomes	19	28%	3	4%	0	0%	5	7%	1	1%
Final say in design	25	37%	15	22%	0	0%	3	4%	0	0%
Conducted statistical analysis	19	28%	26	39%	4	6%	0	0%	1	1%
Drafted manuscript	48	72%	6	9%	0	0%	0	0%	1	1%
Final say on the published manuscript	47	70%	0	0%	0	0%	0	0%	1	1%

Collaborating with funder/ would in the future n=67	Academic, funder and/or CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%
Choice of comparator	23	34%	4	6%	1	1%	0	0%
Choice of outcomes	33	49%	3	4%	3	4%	0	0%
Final say in design	22	33%	0	0%	2	3%	0	0%
Conducted statistical analysis	16	24%	0	0%	0	0%	1	1%
Drafted manuscript	11	16%	0	0%	0	0%	1	1%
Final say on the published manuscript	18	27%	0	0%	0	0%	1	1%

Would not collaborate with funder again or does not know n=8*	Academic		Funder**		CRO**		Regulator		Other***	
	n	%	n	%	n	%	n	%	n	%
Choice of comparator	3	38%	2	25%	0	0%	0	0%	0	0%
Choice of outcomes	4	50%	1	13%	0	0%	0	0%	0	0%
Final say in design	4	50%	2	25%	0	0%	0	0%	0	0%
Conducted statistical analysis	2	25%	2	25%	3	38%	0	0%	0	0%
Drafted manuscript	5	63%	2	25%	0	0%	0	0%	0	0%
Final say on the published manuscript	5	63%	0	0%	0	0%	0	0%	0	0%

Would not collaborate with funder again or does not know n=8*	Academic, funder and/or CRO collaboration		Academic and regulator collaboration		Funder and regulator collaboration		Do not know/Not available	
	n	%	n	%	n	%	n	%
Choice of comparator	1	13%	0	0%	1	13%	1	13%
Choice of outcomes	2	25%	0	0%	0	0%	1	13%
Final say in design	1	13%	0	0%	0	0%	1	13%
Conducted statistical analysis	0	0%	0	0%	0	0%	1	13%
Drafted manuscript	0	0%	0	0%	0	0%	1	13%
Final say on the published manuscript	2	25%	0	0%	0	0%	1	13%

*1 of the 8 authors would not collaborate with funder again, the remaining 7 did not know.
**Funder and CRO also includes unacknowledged persons for the conducted statistical analysis and drafting of manuscript

***Other refers to one trial where it was unclear who had chosen outcomes and conducted statistical analysis and one where the academic did not know who drafted the manuscript and one where the academic found that the journal had the final say on the published manuscript.
Due to rounding the percentages may not add up to 100%.

APPENDIX 7. TABLE 3A

SURVEY REPORTED EXPERIENCE AMONG THE LEAD ACADEMIC AUTHORS STRATIFIED BY INTERVENTION TYPE

	Drug n=61					
	Yes		No		Do not know or Not Available	
	n	%	n	%	n	%
Signed trial agreement with industry funder	50	82%	11	18%	0	0%
Signed trial agreement included a publication agreement*	36	72%	10	20%	3	6%
Signed trial agreement included presentation agreement*	26	52%	18	36%	5	10%
Signed trial agreement included confidentiality agreement*	28	56%	17	34%	4	8%
Had access to the entire trial data set	47	77%	9	15%	5	8%
Access used by those with access to entire data*	42	89%	4	9%	1	2%
Delay in publication due to funder	2	3%	55	90%	4	7%
Disagreements with funder	4	7%	53	87%	4	7%
	Device n=13					
	Yes		No		Do not know or Not Available	
	n	%	n	%	n	%
Signed trial agreement with industry funder	8	62%	5	38%	0	0%
Signed trial agreement included a publication agreement*	5	63%	2	25%	1	13%
Signed trial agreement included presentation agreement*	3	38%	2	25%	3	38%
Signed trial agreement included confidentiality agreement*	7	88%	1	13%	0	0%
Had access to the entire trial data set	11	85%	0	0%	2	15%
Access used by those with access to entire data*	9	82%	2	18%	0	0%
Delay in publication due to funder	1	8%	10	77%	2	15%
Disagreements with funder	4	31%	6	46%	2	15%
	Vaccine n=6					
	Yes		No		Do not know or Not Available	
	n	%	n	%	n	%
Signed trial agreement with industry funder	5	83%	0	0%	1	17%

Signed trial agreement included a publication agreement*	5	100%	0	0%	0	0%
Signed trial agreement included presentation agreement*	4	80%	1	20%	0	0%
Signed trial agreement included confidentiality agreement*	4	80%	1	20%	0	0%
Had access to the entire trial data set	5	83%	0	0%	1	17%
Access used by those with access to entire data*	5	100%	0	0%	0	0%
Delay in publication due to funder	0	0%	5	83%	1	17%
Disagreements with funder	0	0%	5	83%	1	17%

Due to rounding the percentages may not add up to 100%
*n=50, n=8 and n=5 for drug, device and vaccine trials, respectively. Question was only available to those who answered yes to signing an agreement with industry funder
**n=47, n=11 and n=5 for drug, device and vaccine trials, respectively. Question was only available to those who answered yes to data access.

APPENDIX 7. TABLE 3B
SURVEY REPORTED EXPERIENCE AMONG THE LEAD ACADEMIC AUTHORS STRATIFIED AS INDEPENDENT ACADEMIC INDUSTRY-FUNDED TRIALS AND TRIALS WITH FUNDER INVOLVEMENT

	Independent n=4						Funder involved n=76					
	Yes		No		Do not know or Not Available		Yes		No		Do not know or Not Available	
	n	%	n	%	n	%	n	%	n	%	n	%
Signed trial agreement with industry funder	2	50%	2	50%	0	0%	61	80%	14	18%	1	1%
Signed trial agreement included a publication agreement*	1	50%	1	50%	0	0%	45	74%	11	18%	5	8%
Signed trial agreement included presentation agreement*	0	0%	2	100%	0	0%	33	54%	19	31%	9	15%
Signed trial agreement included confidentiality agreement*	0	0%	2	100%	0	0%	39	64%	17	28%	5	8%
Had access to the entire trial data set	3	75%	1	25%	0	0%	60	79%	8	11%	8	11%
Access used by those with access to entire data**	3	100%	0	0%	0	0%	53	88%	6	10%	1	2%
Delay in publication due to funder	1	25%	3	75%	0	0%	2	3%	67	88%	7	9%
Disagreements with funder	0	0%	4	100%	0	0%	9	12%	60	79%	7	9%

Due to rounding the percentages may not add up to 100%
*n=2 and n=61 for independent and funder involved trials, respectively. Question was only available to those who answered yes to signing an agreement with industry funder
**n=3 and n=60 for independent and funder involved trials, respectively. Question was only available to those who answered yes to data access.

APPENDIX 7. TABLE 3C
SURVEY REPORTED EXPERIENCE AMONG THE LEAD ACADEMIC AUTHORS STRATIFIED BY COLLABORATION STATUS

	Collaborating with funder/ would in the future n=67						Would not collaborate with funder again or does not know n=8*					
	Yes		No		Do not know or Not Available		Yes		No		Do not know or Not Available	
	n	%	n	%	n	%	n	%	n	%	n	%
Signed trial agreement with industry funder	56	84%	11	16%	0	0%	4	50%	4	50%	0	0%
Signed trial agreement included a publication agreement**	40	71%	12	21%	3	5%	3	75%	0	0%	1	25%
Signed trial agreement included presentation agreement**	29	52%	20	36%	6	11%	3	75%	0	0%	1	25%
Signed trial agreement included confidentiality agreement**	34	61%	18	32%	3	5%	2	50%	1	25%	1	25%
Had access to the entire trial data set	57	85%	8	12%	2	3%	6	75%	1	13%	1	13%
Access used by those with access to entire data***	49	86%	7	12%	1	2%	6	100%	0	0%	0	0%
Delay in publication due to funder	2	3%	64	96%	1	1%	1	13%	6	75%	1	13%
Disagreements with funder	8	12%	58	87%	1	1%	1	13%	6	75%	1	13%

*1 of the 8 authors would not collaborate with funder again the remaining 7 did not know.
**n=56 and n=4 for collaborating with funder and would not collaborate with funder, respectively. Question was only available to those who answered yes to signing an agreement with industry funder
***n=56 and n=4 for collaborating with funder and would not collaborate with funder, respectively. Question was only available to those who answered yes to data access
Due to rounding the percentages may not add up to 100%.